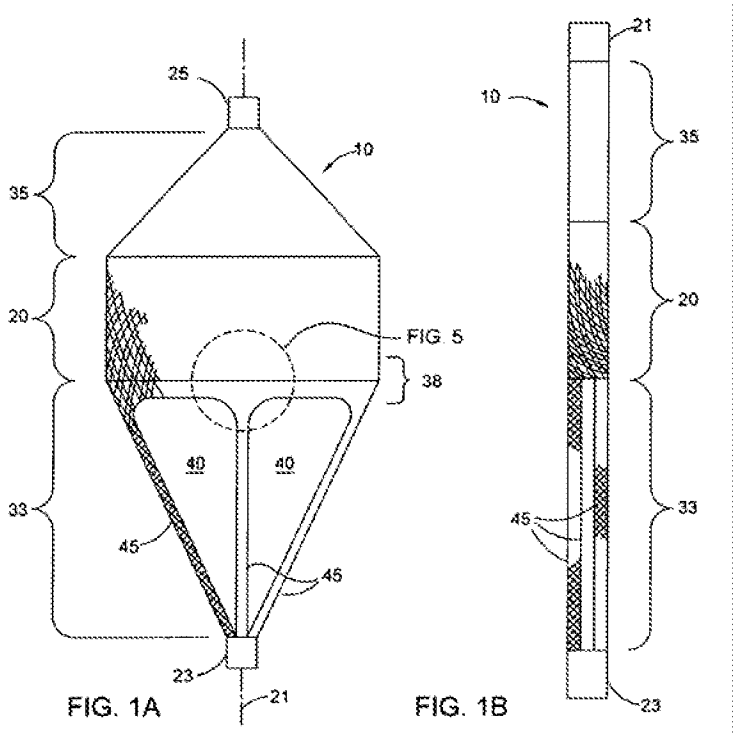
REMARKS/ARGUMENTS

The foregoing amendments have been made in response to the official action of February 13, 2008. Claim 1 has been amended to define further that each strand is intra-braided solely from a plurality of filaments of the second array and that none of the strands is braided with any other strand whereby the space between adjacent strands defines an unobstructed filter inlet port. Claim 15 has been added.

APPLICANTS' INVENTION

Applicants' invention relates to a construction of a temporary intraluminal vascular filter for capturing and removing emboli from a blood vessel during an interventional vascular procedure. The filter is formed from braided filaments and is illustrated in its expanded, deployed configuration and its collapsed configuration in FIGS. 1A and 1B, respectively, reproduced below.



The filter includes a cylindrical filter body 20 adapted to expand against the inner wall of the patient's vessel, a tapered distal section 35 and a tapered proximal section 33. Proximal and distal end members 23, 25 are attachable to a delivery device such as a catheter or hollow wire-

like shaft coupled to the filter proximal end 23 and a movable core wire coupled to filter distal end 25. The filter may be expanded or contracted by push-pull operation of the shaft and core wire.

A significant objective of the invention is to provide an improved filter construction that reduces accumulation of embolic debris outside the filter on upstream, proximally facing surfaces, particularly between or about the inlet ports. As explained in the written description, such accumulation may allow debris to break free and escape past the filter as the filter is closed preparatory to its removal from the patient. The filter construction is adapted to reduce that risk while also providing enlarged inlet ports at the proximal end of the filter to maximize the entrapment of debris in a filter that is simple to manufacture, while also providing good structural integrity.

The filter is formed from two arrays of filaments including first array filaments 53 and second array filaments 63. The filaments 53 in the first array extend from the distal end 25 to a region of junction 38 of the filter body 20 and proximal section 33. Filaments 63 extend from the distal end 25 all the way to the proximal end 23 of the filter. The filaments 53 and 63 are braided together (inter-braided) to form the distal section 35 and filter body 20. The braiding is sufficiently dense so that no additional filter material is necessary.

The filaments 53 in the first array are severed to terminate in the junction region 38. The filaments 63 in the second array extend proximally beyond the junction region to the proximal end and are divided into two or more groups with each group forming a plurality of filaments that are braided (intra-braided) together to compose a strong narrow strand 45. The strands 45 are slender and have a small combined surface area with the space between the strands defining large unobstructed inlet ports 40. The enlarged ports 40 enhance blood flow into the filter with reduced likelihood of particulate matter accumulating on the external surfaces of the slender braided strands 45. The strands 45 extend the full length of the proximal section 33 and have a braided construction that enhances the structural integrity of the device.

CITED PRIOR ART

U.S. Patent 6,375,670 (Greenhalgh)

Greenhalgh discloses a braided intraluminal filter as illustrated in FIG. 1, reproduced below.

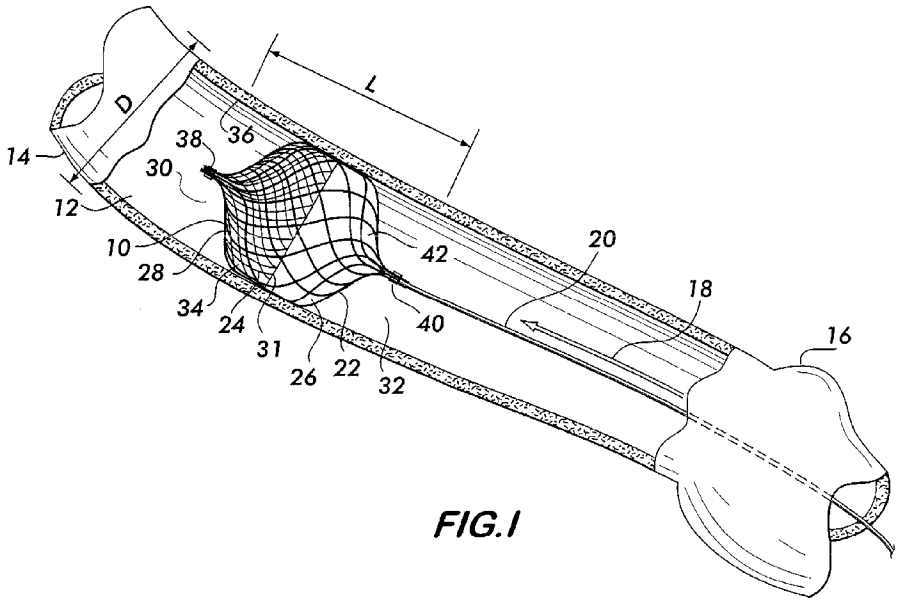


FIG.1

The filter 10 includes an open mesh basket 26 formed from wires 22 loosely braided to form a support for a filter element 28 made from braided polymer (polyester) textile yarns 24 arranged in a densely braided mesh 34. Although the yarns are said to be co-braided with the metal wires 22, there is no description that the wires 22 form any part of the filter other than as a support for the yarn mesh 34. (4:61-65). The wires 22 are said to define an open mesh basket to form entrance openings 42 to allow blood or other fluid to flow into the filter (6:34-40) and serve as a support structure for the filter element 20. The porosity of the filter element is controlled by varying the denier of the yarn and the mesh density (5:48-49).

U.S. Patent 6,336,934 (Gilson)

Gilson '934 discloses a variety of embolic protection devices with the device shown in FIG. 39 indicated in the action as being relevant. FIG. 39 is reproduced below.

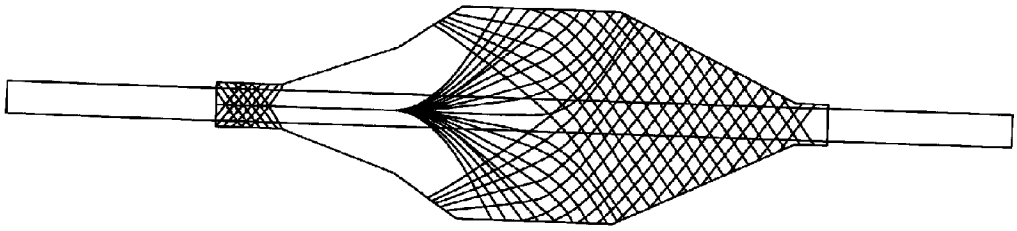


FIG. 39

The sole reference to FIG. 39 in Gilson is in the description of the drawings in which it is described as showing "...a fibrous mesh filter design with fibers woven at the distal end and converging into a number of bundles at the proximal end;" (8:46-48). Elsewhere, at 6:42-47, Gilson states that "Larger proximal inlet holes are provided by the convergence of the fibers of the braid into a few bundles which are mounted to the filter carrier." It is not clear whether the latter statement is intended to refer to the FIG. 39 embodiment. The figure has no reference numerals and there is no mention or discussion of FIG. 39 in the written description.

U.S. Patent Application 2003/0097094 (Ouriel)

The Ouriel application discloses method and apparatus for dislodging and capturing thrombus in a blood vessel and delivering thrombolytic fluid to the thrombus to dissolve the thrombus. FIG. 13, reproduced below, is said to be relevant to the rejection.

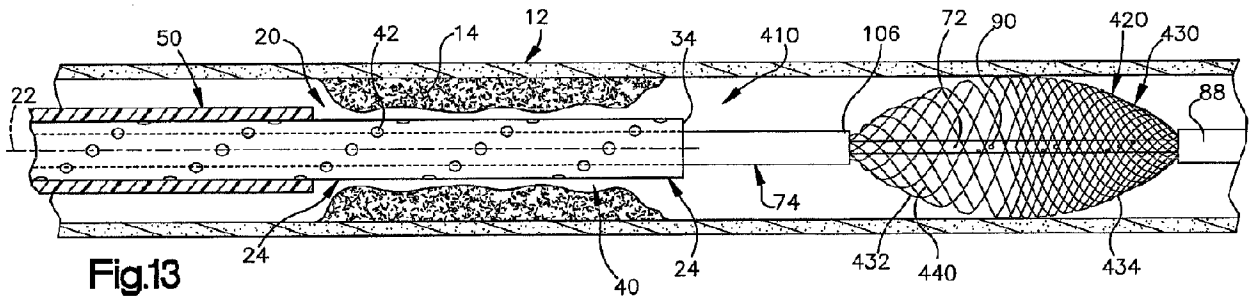


Fig.13

The device includes several tubular elements including a first catheter 24 having a plurality of infusion ports 42, a sleeve 74 contained within the first catheter and a second catheter 72 contained within the sleeve 74. The second catheter also has infusion ports 90. The infusion ports 42, 90 are arranged first to deliver a thrombolytic fluid to cause thrombus 14 to dislodge

from the inner surface 16 of the blood vessel (see FIG. 5) and break into dislodged fragments. The thrombolytic fluid is said to break down the thrombotic material and cause its dissolution. (paragraph 0043). The device includes a radially expandable filter 420, one end of which is attached to the distal end of the second catheter 72 and the other end is attached to the sleeve 74. The filter 420 defines a filter basket 430 with a proximal half 432 having a loose mesh to allow dislodged thrombotic material 78 to enter the filter and a distal half 434 with a relatively tight mesh to trap the dislodged thrombotic material 78 as blood flows through the filter. (paragraph 0066). The filter basket 430 is made of wires 440 that are said to be braided into wire bundles to form the relatively loose mesh of the proximal half 432 of the filter basket. The wires 440 form the tight mesh in the distal half 434 of the filter basket 430. (paragraph 0067). The bundled wires are shown in FIG. 13 as being interwoven in a loose mesh.

CLAIM REJECTIONS – 35 U.S.C. §103

Reconsideration is requested of the rejection of claims 1-3 and 6-10 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Greenhalgh '670, Gilson '934 and Ouriel application '094. Greenhalgh differs in a number of respects from applicants' invention as defined in claim 1. Greenhalgh discloses an open mesh basket formed from wires 22 that are loosely braided at the proximal and distal portions of the basket. The basket does not function as a filter but, instead, serves as a support for a separate filter 28 formed from polyester yarns 24 arranged in a densely braided mesh. Some of the polyester yarns 24 in the filter mesh 28 are said to be attached to the metal wires 22 of the basket 26 by cobraiding. None of the yarns 24 in Greenhalgh's filter 28 extend into the proximal portion of the filter basket. Additionally, as acknowledged in the official action, Greenhalgh does not disclose that the filaments of the second array are intra-braided to form two or more strands in the filter proximal section. The wires 22 in Greenhalgh have the same loose open braid in the distal section of the filter as in the proximal section and none serve as a filtering element.

Ouriel is similar in some respects to Greenhalgh in that it also discloses a filter device with wires braided or woven in a loose mesh along the proximal portion of the filter. The wires are arranged in a tighter mesh at the distal half of the filter and appear themselves to be arranged to provide a filtering function. FIG. 13 in Ouriel fails to disclose a first array of braided

filaments that extend proximally from the filter distal end to a proximal terminus between a cylindrical body and a tapered proximal section. Although Ouriel mentions the bundling of wires, the bundles themselves are then braided or woven in the proximal section.

To the extent that the rejection relies on Gilson, it necessarily interprets Gilson in light of applicants' disclosure. The Gilson disclosure is very sparse, consisting essentially of a drawing without reference numerals, without any detailed description and with the only description of FIG. 39 being in the summary of the drawings in which it is said to show "...a fibrous mesh filter design with fibers woven at the distal end and converging into a number of bundles at the proximal end;". FIG. 39, of course, must be interpreted without reference to applicants' disclosure because to do so would constitute impermissible hindsight reasoning. FIG. 39 is again reproduced below with reference numerals added in an attempt to correspond the drawing with the scant "disclosure".

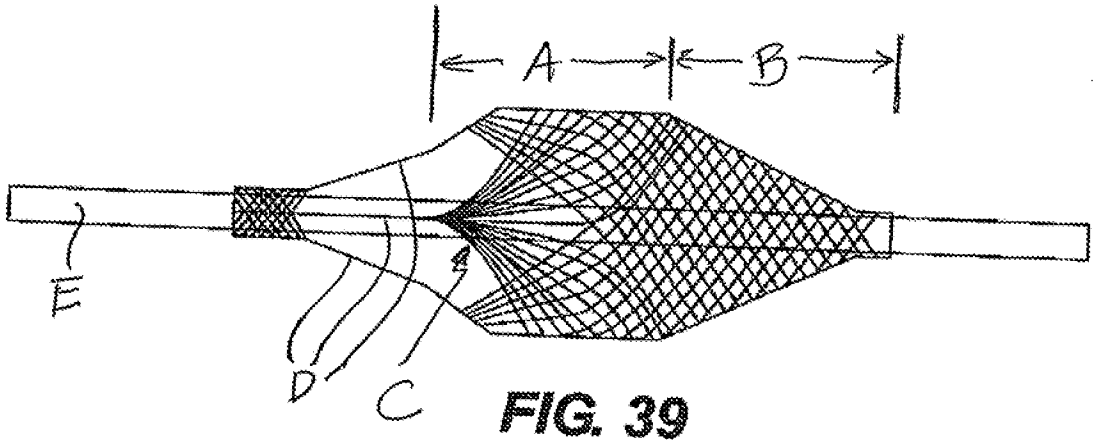


FIG. 39

The region identified as "B" above appears to disclose the fibrous mesh of woven fibers. The region labeled "A" appears to correspond to the woven fibers said to converge into a number of bundles. The only bundles apparent in FIG. 39 are those that are identified immediately above as "C". The bundles "C" appear to be connected to a shaft "E" by individual fibers "D". There is no disclosure that what appear to be individual fibers "D" are, in fact, formed from intra-braided filaments of a second array. Indeed, the converging fibers in the proximal portion of the region "A", including the region "C", do not appear to be woven or braided at all. Instead, they appear to separate from a woven region and extend, somehow, without braiding or weaving to a

point at which they are connected to the apparent individual wires "D". Any other interpretation necessarily would have to rely on applicants' disclosure and would constitute impermissible hindsight reasoning.

It also should be noted that the FIG. 39 drawing does not show anything that might be considered as a first array of fibers that extend proximally from the distal end of the filter to a proximal terminus. As near as can be determined from FIG. 39 all of the fibers, not just one group of fibers, extend from the distal end to the region of convergence "C".

The rejection is improper in that it is based in part on an interpretation of Gilson that is improperly informed and colored by applicants' disclosure. The rejection of claim 1 should be withdrawn.

Reconsideration is requested of the rejection of claims 6-10 for the same reasons discussed above in connection with claim 1, from which each of claims 6-10 depends directly or indirectly. Additionally, claim 6 includes the further limitation of a retention member in the form of joints formed where the filaments of the first array overlap filaments of the second array. The rejection fails to point out where any of the references discloses this limitation. Claim 7 includes the same limitations as claim 6 and further specifies a number of joining methods.

Reconsideration is requested of the rejection of claims 4 and 5 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Greenhalgh, Gilson, Ouriel and Hyodoh. Claims 4 and 5 each depend directly or indirectly from claim 1 and are patentable for the same reasons. Hyodoh fails to disclose those features of applicants' invention that are missing from Greenhalgh, Gilson and Ouriel, as discussed above. As to Hyodoh, it does not disclose the claimed retention member. The retention member is said to couple the proximal terminus of the filaments of the first array with filaments of the second array. There are no filaments with the claimed proximal terminus in Hyodoh. Moreover, the element in Hyodoh, said to be an encapsulating sleeve, appears to be described in paragraph 0230 to refer to a stretchable jacket that is configured to cover at least a portion of the body of an occluder. In order for the device in Hyodoh to serve as an occluder, at least half of the apparently woven mesh would have to be completely covered to prevent any flow through the device. Thus, the device could not serve as a filter, as called for by applicants' claims. For applicants' claimed device to function as a filter, flow, not occlusion is required. Covering a filter with an enclosing sleeve to occlude flow would

destroy its filtering function. Additionally, to the extent that the action relies on reference numeral 710, that element is not mentioned in paragraph 0230 with regard to the stretchable jacket, and element 710 does not disclose an encapsulating sleeve of any kind. Rather, 710 is said to refer to metal clips to hold the closed structures of the body together (paragraph 0231) or "loops" (paragraph 0234, 0236).

Reconsideration is requested of the rejection of claims 11-14 as unpatentable under 35 U.S.C. §103(a) over the combined disclosures of Greenhalgh, Gilson, Ouriel and Molgaard-Nielsen '246. This rejection again interprets the Gilson disclosure of FIG. 39 stating that "**...**the strands of the proximal section are bundled together into two or more strands." While Gilson FIG. 39 appears to disclose convergence of all of the fibers into bundles, there is no mention or explanation of strands. See the discussion above with respect to claim 1. As discussed above, the interpretation of Gilson in the official action necessarily relies on applicants' disclosure and is improper hindsight reasoning. Molgaard-Nielsen fails to disclose those features of applicants' invention discussed above.

THE LEVEL OF SKILL IN THE ART

Response to applicants' argument concerning the level of skill is circular and does not resolve the matter. Merely to say that the level of skill applied was that of "one of ordinary skill in the art" does not provide a basis from which one can determine what was considered as ordinary. It is applicants' position that an explanation is required as to the basis of what was considered as "ordinary". That is necessary in order for one to test whether the proper level was applied.

Respectfully submitted,

/James F. Crittenden/
Registration No. 39,560
Agent for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No. (707) 543-5420